NRDC
THE EARTH'S BEST DEFENSE

NATURAL RESOURCES DEFENSE COUNCIL

May 20, 2002

BY FACSIMILE

Office of the Hearing Clerk
U.S. Environmental Protection Agency
Room C400, Waterside Mall
401 M Street, S.W.
Washington, D.C. 20460

Docket Nos: OPP 301224; OPP 301225; OPP 301221; OPP 301223; OPP 301228; OPP 2002-0003.

Re: Objections to the Establishment of Tolerances for Isoxadifen-ethyl, Acetamiprid, Propiconazole, Furilazole, Fenhexamid, and Fluazinam.

Dear Hearing Clerk:

On behalf of the Natural Resources Defense Council, I am submitting objections to the establishment of tolerances for the following pesticide chemical residues: Isoxadifen-ethyl (OPP 301224), Acetamiprid (OPP 301225), Propiconazole (OPP 301221), Furilazole (301223), Fenhexamid (OPP 301228), and Fluazinam (OPP 2002-0003).

I am forwarding separate copies of these objections to the Registration Division contacts for each chemical. I am also forwarding copies for each docket to the Public Information Records and Integrity Branch, Information Resources and Services Division.

Thank you for your assistance. Please contact me at (202) 289-2376 if you have any questions regarding these objections.

Sincerely,

Aaron Colangelo

Encl.

www.nrdc.org 1200 New York Avenue, NW, Suite 400
Washington, DC 20005
TEL 202 289-6868 FAX 202 289-1060

NEW YORK • LOS ANGELES • SAN FRANCISCO

OBJECTIONS
TO THE ESTABLISHMENT OF TOLERANCES
FOR PESTICIDE CHEMICAL RESIDUES

OPP 301224 (Isoxadifen-ethyl)
OPP 301225 (Acetamiprid)
OPP 301221 (Propiconazole)
OPP 301223 (Furilazole)
OPP 301228 (Fenhexamid)
OPP 2002-0003 (Fluazinam)

Pursuant to 21 U.S.C. § 346a(g) and 40 C.F.R. Part 180, the Natural Resources Defense Council (NRDC) makes the following objections:

(1) NRDC objects to the regulation issued under 21 U.S.C. § 346a(d)(4), establishing a tolerance for pesticide chemical residues of isoxadifen-ethyl. 67 Fed. Reg. 12,875 (March 20, 2002).

(2) NRDC objects to the regulation issued under 21 U.S.C. § 346a(d)(4), establishing a tolerance for pesticide chemical residues of acetamiprid. 67 Fed. Reg. 14,649 (March 27, 2002).

(3) NRDC objects to the regulation issued under 21 U.S.C. § 346a(*l*)(6), establishing a time-limited tolerance for pesticide chemical residues of propiconazole until December 31, 2003. 67 Fed. Reg. 14,866 (March 28, 2002).

(4) NRDC objects to the regulation issued under 21 U.S.C. § 346a(d)(4), establishing a tolerance for pesticide chemical residues of furilazole. 67 Fed. Reg. 15,727 (April 3, 2002).

(5) NRDC objects to the regulation issued under 21 U.S.C. § 346a(d)(4), establishing a tolerance for pesticide chemical residues of fenhexamid. 67 Fed. Reg. 19,114 (April 18, 2002).

(6) NRDC objects to the regulation issued under 21 U.S.C. § 346a(d)(4), establishing a tolerance for pesticide chemical residues of fluazinam. 67 Fed. Reg. 19,120 (April 18, 2002).

As discussed further below, NRDC requests a waiver of the tolerance objection fees pursuant to 40 C.F.R. 180.33(m).

I. SUPPORTING MATERIAL

NRDC incorporates by reference the following attachments in support of these objections:

Attachment A: NRDC et al., *Petition for a Directive that the Agency Consistently Fulfill Its Duty to Retain the Child-Protective Tenfold Safety Factor Mandated by the Food Quality Protection Act*, April 23, 1998 (available online at http://www.ecologic-ipm.com/petition.html).

Attachment B: NRDC et al., *Petition for a Directive that the Agency Designate Farm Children As a Major Identifiable Subgroup and Population at Special Risk to be Protected under the Food Quality Protection Act,* Oct. 22, 1998 (available online at http://www.ecologic-ipm.com/farmkids.PDF).

Attachment C: NRDC, *Putting Children First: Making Pesticide Levels in Food Safer for Infants and Children*, April 1998 (executive summary available online at http://www.nrdc.org/health/kids/rpcfsum.asp).

Attachment D: NRDC, *Trouble on the Farm: Growing up with Pesticides in Agricultural Communities*, October 1998 (available online at http://www.nrdc.org/health/kids/farm/farminx.asp).

Attachment E: U.S. General Accounting Office, *Pesticides: Improvements Needed to Ensure the Safety of Farmworkers and Their Children*, (RCED-00-40), March 14, 2000 (available online at http://www.gao.gov/).

Attachment F: Lymphoma Foundation of America, *Do Pesticides Cause Lymphoma?*, 2001 (available online at http://www.lymphomahelp.org/docs/research/researchreport/rr_2000.pdf).

NRDC reserves the right to submit additional supplemental information in further support of these objections.

II. INTRODUCTION

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA), the Environmental Protection Agency (EPA) may only establish a tolerance for pesticide chemical residues in or on a food if EPA determines that the tolerance is "safe." 21 U.S.C. § 346a(b)(2)(A)(i). A tolerance will meet this requirement only if "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." *Id.* § 346a(b)(2)(A)(ii). The health-protective standard of the FQPA requires EPA to give special consideration to the health of infants and children, and EPA must "ensure that

there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue." *Id.* § 346a(b)(2)(C)(ii)(i).

EPA has violated the requirements of the FQPA in establishing new tolerances for isoxadifen-ethyl, acetamiprid, propiconazole, furilazole, fenhexamid, and fluazinam – published at 67 Fed. Reg. 12,875 (March 20, 2002) (isoxadifen-ethyl), 67 Fed. Reg. 14,649 (March 27, 2002) (acetamiprid), 67 Fed. Reg. 14,866 (March 28, 2002) (propiconazole), 67 Fed. Reg. 15,727 (April 3, 2002) (furilazole), 67 Fed. Reg. 19,114 (April 18, 2002) (fenhexamid), and 67 Fed. Reg. 19,120 (April 18, 2002) (fluazinam). With respect to all six pesticides, EPA failed to apply the children's 10X safety factor properly, acknowledge and consider farm children as a major identifiable subgroup, take into consideration reliable data concerning occupational exposure, fully assess aggregate exposures, or regulate on the basis of a no-observed-effect-level. With respect to isoxadifen-ethyl, acetamiprid, and furilazole, EPA additionally failed to protect all infants and children and not just those within a certain percentile, and as a result left potentially more than a million children unprotected. Finally, for propiconazole and fluazinam, EPA failed to guarantee that legal food will be safe food based on exposure to pesticide chemical residues at the tolerance level.

III. GROUNDS FOR THE OBJECTIONS

A. In Establishing These Tolerances, EPA Improperly Failed To Apply The Children's 10X Safety Factor.

In establishing tolerances for isoxadifen-ethyl, acetamiprid, propiconazole, furilazole, fenhexamid, and fluazinam, EPA failed to include the full additional 10X safety factor for infants and children as required by the FQPA. Under the Food Quality Protection Act's precautionary approach to protecting children, EPA must maintain an

additional 10-fold margin of safety in its risk assessments for individual pesticides to "take into account potential pre– and post–natal developmental toxicity and completeness of the data with respect to exposure and toxicity to infants and children." 21 U.S.C. § 346a(b)(2)(C). EPA can use a different margin of safety "only if, on the basis of reliable data, such margin will be safe for infants and children." *Id.* Yet there are significant toxicity and exposure data gaps for each of these new tolerances established by EPA. In addition, EPA has acknowledged that it lacks necessary and required data to assess toxicity to the developing brain and nervous system for acetamiprid and fluazinam in particular, and therefore lacks the "reliable data" necessary under the FQPA to authorize a different margin of safety.

For all six pesticides EPA failed adequately to consider important exposure routes for millions of infants and children, including exposure to children living on farms and who accompany their parents into farm fields (see discussion of farm children below), and exposure from spray drift. Furthermore, for all six pesticides, EPA has failed to collect pesticide-specific data on water-based exposure, rendering it impossible to find that "reliable data" exist to reduce the tenfold safety factor. 66 Fed. Reg. 33,180, 33,183 (isoxadifen-ethyl); 67 Fed. Reg. 14,649, 14,654 (acetamiprid); 64 Fed. Reg. 2995, 2998 (propiconazole); 67 Fed. Reg. 19,114, 19,116 (fenhexamid); 67 Fed. Reg. 19,120, 19,126 (fluazinam); 67 Fed. Reg. 15,727, 15,731 (furilazole). The use of predictive models to estimate drinking water exposure to these pesticides serves as a stop-gap measure, but cannot take the place of actual "reliable data" that justify removing the statutory tenfold safety factor. Because EPA has used modeling scenarios to approximate drinking water exposure to these pesticides, it has not relied on any data at all – only predictions that are,

in NRDC's view, not conservative. Relying only on modeling results, in the absence of any reliable and confirmatory monitoring data, results in an additional data gap that prevents EPA from overturning the presumptive 10X safety factor. All of these deficiencies in toxicity and exposure data preclude EPA's removal of the presumptive 10X safety factor. 21 U.S.C. § 346a(b)(2)(C).

In addition, the regulations establishing new tolerances for isoxadifen-ethyl, acetamiprid, propiconazole, furilazole, fenhexamid, and fluazinam reveal further toxicity and exposure data gaps for each pesticide. Missing data for isoxadifen-ethyl includes residential short-term and intermediate-term risk assessments. 66 Fed. Reg. 33,179, 33,185. Missing data for acetamiprid includes oral exposure from residential uses and a developmental neurotoxicity study. 67 Fed. Reg. 14,649, 14,654, 14,655. Data gaps for propiconazole include all residential risk assessments. 64 Fed. Reg. 2995, 2999. Missing data for fenhexamid includes residential short-term and intermediate-term risk assessments. 67 Fed. Reg. 19,114, 19,118. Data gaps for fluazinam include a cancer assessment, a developmental neurotoxicity study, a 28-day inhalation toxicity study, and a conditional requirement of a subchronic neurotoxicity screening battery. 67 Fed. Reg. 19,120, 19,126, 19,128. Finally, missing data for furilazole includes the lack of a chronic dog study. 67 Fed. Reg. 15,727, 15,730.

The absence of required developmental neurotoxicity (DNT) tests for acetamiprid and fluazinam is a crucial data gap that by itself should prohibit EPA from overturning the default 10X safety factor. In its 1993 report, Pesticides in the Diets of Infants and Children, the National Academy of Sciences/National Research Council cited strong evidence that pesticide exposures may disrupt the normal development of a child's brain

and nervous system. More conclusive evidence has since been published supporting this finding.[1] Studies by EPA staff scientist Dr. Makris show that DNT testing is more sensitive than other studies in measuring the effects of exposure on proper development of the brain and nervous system, and therefore DNT testing is more appropriate for protecting children's health. DNT testing is essential for pesticides, not only as a measure of toxicity to the developing brain and nervous system, but also as an often more sensitive measure of developmental and reproductive effects generally.[2] EPA's 10X Task Force has recommended that "developmental neurotoxicity testing be included as part of the minimum core toxicology data set for all chemical food-use pesticides for which a tolerance would be set." *See* 10X Task Force, U.S. Environmental Protection Agency, *Toxicology Data Requirements for Assessing Risks of Pesticide Exposure to Children's Health (draft)*, Nov. 30, 1998, at 11. Although DNT testing has not yet been incorporated in the minimum core toxicology data set for all pesticides, EPA has required DNT studies on a case-by-case basis for particular pesticides, including acetamiprid and fluazinam. 67 Fed. Reg. 14,649, 14,655 (acetamiprid); 67 Fed. Reg. 19,120, 19,126

---

[1] Crumpton TL, Seidler FJ, Slotkin TA. Developmental neurotoxicity of chlorpyrifos in vivo and in vitro: effects on nuclear transcription factors involved in cell replication and differentiation. Brain Res 2000; 857:87-98; Dam K, Seidler FJ, Slotkin TA. Developmental neurotoxicity of chlorpyrifos: delayed targeting of DNA synthesis after repeated administration. Brain Res Dev Brain Res 1998; 108:39-45; Dam K, Seidler FJ, Slotkin TA. Chlorpyrifos releases norepinephrine from adult and neonatal rat brain synaptosomes. Brain Res Dev Brain Res 1999; 118:129-33; Dam K, Garcia SJ, Seidler FJ, Slotkin TA. Neonatal chlorpyrifos exposure alters synaptic development and neuronal activity in cholinergic and catecholaminergic pathways. Brain Res Dev Brain Res 1999; 116:9-20; Dam K, Seidler FJ, Slotkin TA. Chlorpyrifos exposure during a critical neonatal period elicits gender- selective deficits in the development of coordination skills and locomotor activity. Brain Res Dev Brain Res 2000; 121:179-87; Levin ED, Addy N, Nakajima A, Christopher NC, Seidler FJ, Slotkin TA. Persistent behavioral consequences of neonatal chlorpyrifos exposure in rats. Brain Res Dev Brain Res 2001; 130:83-9; Raines KW, Seidler FJ, Slotkin TA. Alterations in serotonin transporter expression in brain regions of rats exposed neonatally to chlorpyrifos. Brain Res Dev Brain Res 2001; 130:65-72.

[2] Kimmel CA, Makris SL. Recent developments in regulatory requirements for developmental toxicology. Toxicol Lett 2001; 120:73-82.

(fluazinam). In spite of this, in establishing new tolerances, the Agency failed to retain the presumptive FQPA 10X safety factor for either of these pesticides.

EPA has expressly acknowledged that DNT testing is necessary and required to assess the risks of acetamiprid and fluazinam, and these studies are still missing. 67 Fed. Reg. 14,655; 67 Fed. Reg. 19,126. These critical data gaps make it impossible to assess the neurotoxic effects of these pesticides to fetuses, infants, and children. The FQPA neither requires nor justifies regulatory delay in order to collect this additional data. The potential future submission of DNT studies for these pesticides does not justify removing 10X in anticipation of those studies; EPA must use the ten-fold safety factor to protect children's health while the data is missing. 21 U.S.C. § 346a(b)(2)(C). Even though these conditions have been unfulfilled, EPA has established new tolerances for acetamiprid and fluazinam. In doing so, EPA failed to apply the required 10X safety factor for children that is intended to compensate for just such data gaps. *Id.*

EPA's recently released 10X policy paper attempts to justify the Agency's decision to ignore 10X even in the absence of required DNT studies. *See* Office of Pesticide Programs, U.S. Environmental Protection Agency, *Determination of the Appropriate FQPA Safety Factor(s) in Tolerance Assessment*, Feb. 28, 2002, at 23-25. EPA states: "[s]imply because OPP has required a DNT for a particular pesticide does not necessarily mean that a database uncertainty factor is needed. However, if the available information indicates that a DNT study is likely to identify a new hazard or effects at lower dose levels of the pesticide that could significantly change the outcome of its overall risk assessment, the database uncertainty factor should be considered." *Id.* at 24. This position is untenable. The FQPA requires that an additional 10X safety factor must

be applied; this burden can be overcome "only if, on the basis of reliable data, such margin will be safe for infants and children." 21 U.S.C. § 346a(b)(2)(C). EPA's approach to required DNT studies completely reverses this presumption and declares that, *even in the absence of required data on neurotoxicity for developing fetuses, infants, and children*, the default 10X safety factor can be removed if the missing data is not "expected" to "significantly change the outcome" of the overall risk assessment. Under this approach, the removal of the safety factor is based not upon the statutorily demanded "reliable data," but upon the risk assessor's expectation—his or her intuition or professional judgment. The FQPA cannot accommodate this counterintuitive and underprotective approach. EPA has required DNT tests for acetamiprid and fluazinam, and these studies have not been conducted. EPA therefore cannot argue that "reliable data" justifies removing the statutory presumptive 10X FQPA safety factor.

Had EPA not removed 10X, many of these pesticide tolerances would have been acknowledged to be unsafe. Even ignoring all of the other flaws in EPA's tolerance regulations for these pesticides (addressed below), *this single decision to overturn 10X resulted in unsafe tolerances improperly being declared "safe."*

- For acetamiprid, EPA calculated that the margin of exposure (MOE) for short-term and intermediate-term aggregate exposure for children aged one to six was 1,021. 67 Fed. Reg. 14,657. Relying on an FQPA safety factor of 3X instead of 10X, EPA established a "safe" MOE of 300. But if EPA had applied 10X, as it was obligated to do under the FQPA, the safe MOE would have been 1000, and the actual MOE would have been acknowledged to be dangerously close to the safe MOE for this highly vulnerable population group. EPA also calculated the

MOE for short-term and intermediate-term residential exposure to be 189 for adults and 239 for kids aged 10-12. 67 Fed. Reg. 14,655. These margins of exposure are below the level of 300 declared to be safe by the Agency, and would be well below an MOE of 1000. Therefore, the new tolerance for acetamiprid should not have been established.

- For propiconazole, EPA calculated the actual margin of exposure for short-term dermal exposure to be 200. 64 Fed. Reg. 2999. At the same time, EPA relied on an FQPA safety factor of only 1X (in other words, no FQPA safety factor at all), to establish a "safe" MOE of 100, and thus declared that the actual margin of exposure was safe. *Id.* Yet if EPA has properly applied the presumptive 10X FQPA safety factor, the safe MOE would have been set at 1000 instead of 100, *the above actual MOE would have been acknowledged as unsafe*, and the new tolerance for propiconazole could not have been established.

In light of the incomplete data and potential pre- and post-natal developmental toxicity for isoxadifen-ethyl, acetamiprid, propiconazole, furilazole, fenhexamid, and fluazinam, EPA's failure to apply the 10X children's safety factor violates the FQPA and EPA's own stated policy on proper application of the 10X safety factor. *See* Office of Pesticide Programs, U.S. Environmental Protection Agency, *Determination of the Appropriate FQPA Safety Factor(s) in Tolerance Assessment*, Feb. 28, 2002, at 11 ("Risk assessors . . . should presume that the default 10X safety factor applies and should only recommend a different factor, based on an individualized assessment, when reliable data show that such a different factor is safe for infants and children."). The absence of required DNT studies for acetamiprid and fluazinam make EPA's failure to apply 10X

for these pesticides especially egregious. EPA lacks reliable data to overturn the presumption of a 10X FQPA safety factor for any of the six pesticides addressed in these objections. Where there are no data or where there are gaps in data – either for particular toxic effects, for specific patterns of food consumption, or for particular routes of exposure – there cannot be the "reliable data" required by the FQPA to remove 10X.

B. Farm Children Are Especially Vulnerable To Pesticide Exposure, And Are Not Adequately Considered In These Tolerances.

Farm children should be deemed to comprise an especially vulnerable population, and their exposure to isoxadifen-ethyl, acetamiprid, propiconazole, furilazole, fenhexamid, and fluazinam must be considered in establishing tolerances where data is available. The FQPA requires that EPA consider exposure not just to consumers as a whole, but also to "major identifiable subgroups of consumers." 21 U.S.C. § 346a(b)(2)(D). In establishing tolerances, EPA must consider, among other relevant factors, "available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers); . . . available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers);" and "available information concerning the variability of the sensitivities of major identifiable subgroups of consumers." 21 U.S.C. § 346a(b)(2)(D)(iv); (vi); (vii). Farm children are a major identifiable subgroup under these statutory provisions, and their unique dietary consumption patterns, aggregate exposure levels, and sensitivities to exposure should have been assessed by EPA in establishing new tolerances for isoxadifen-ethyl, acetamiprid, propiconazole, furilazole, fenhexamid, and fluazinam.

More than 320,000 children under the age of six live on farms in the United States. In addition, many hundreds of thousands of children play or attend schools on or

near agricultural land, and others have family members who work on farms or handle pesticides as part of their jobs. The nation's 2.5 million farm workers have approximately one million children living in the United States. *See* NRDC et al., *Petition for a Directive that the Agency Designate Farm Children As a Major Identifiable Subgroup and Population at Special Risk to be Protected under the Food Quality Protection Act,* Oct. 22, 1998, at 1 (hereafter "NRDC, *Farm Kids Petition"*).

Children living in agricultural communities are heavily exposed to pesticides, whether or not they work in the fields.[3] Farm children come in contact with pesticides through residues from their parents' clothing, dust tracked into their homes, contaminated soil in areas where they play, food eaten directly from the fields, drift from aerial spraying, contaminated well water, and breastmilk. Furthermore, farm children often accompany their parents to work in the fields, raising their pesticide exposures even higher. *See* NRDC, *Farm Kids Petition*, at 2-3. Citing data from the Department of Labor, the U.S. General Accounting Office has reported that seven percent of farmworkers with children five years old or younger took their children with them when they worked in the fields. *See* U.S. General Accounting Office, *Pesticides: Improvements Needed to Ensure the Safety of Farmworkers and Their Children*, (RCED-00-40), March 14, 2000, at 6 (hereafter "GAO, *Safety of Farmworkers and Their Children"*). Children age nine or older may and do work on large farms. Farm children are likely to have the highest exposure to pesticides of any group of people in the

[3] Lu C, Fenske RA, Simcox NJ, Kalman D. Pesticide exposure of children in an agricultural community: evidence of household proximity to farmland and take home exposure pathways. Environ Res 2000; 84:290-302; Loewenherz C, Fenske RA, Simcox NJ, Bellamy G, Kalman D. Biological monitoring of organophosphorus pesticide exposure among children of agricultural workers in central Washington State. Environ Health Perspect 1997; 105:1344-53; Fenske RA. Pesticide exposure assessment of workers and their families. Occup Med 1997; 12:221-37.

country. Many of the children with the greatest pesticide exposures are from migrant farmworker families, who are poor and usually people of color or recent immigrants. *See* NRDC, *Farm Kids Petition*, at 2-3.

Children have unique exposure patterns and sensitivities to pesticides. Per pound of body weight, children eat, drink, and breathe more than adults. Children also engage in more frequent hand-to-mouth contact, and therefore have higher rates of oral exposure from objects, dust, or soil. *See* NRDC, *Farm Kids Petition*, at 3; GAO, *Safety of Farmworkers and Their Children*, at 17. The GAO found that crawling, sitting, and lying on contaminated surfaces may also increase exposure rates of farm children to pesticides. *See* GAO, *Safety of Farmworkers and Their Children*, at 17. Furthermore, as the GAO concluded, "[b]ecause young children's internal organs and bodily processes are still developing and maturing, their enzymatic, metabolic, and immune systems may provide less natural protection than those of an adult." *Id.*

EPA's regulations establishing tolerances for isoxadifen-ethyl, acetamiprid, propiconazole, furilazole, fenhexamid, and fluazinam fail to consider information concerning the sensitivities and exposures of farm children as a major identifiable subgroup. 66 Fed. Reg. 33,179 (isoxadifen-ethyl); 67 Fed. Reg. 14,649 (acetamiprid); 64 Fed. Reg. 2995 (propiconazole); 67 Fed. Reg. 15,727 (furilazole); 67 Fed. Reg. 19,114 (fenhexamid); 67 Fed. Reg. 19,120 (fluazinam). Under the FQPA, 21 U.S.C. § 346a(b)(2)(D), EPA must consider data regarding farm children's dietary consumption patterns, aggregate exposure levels, and sensitivities to exposure. If reliable data are lacking, EPA must require the pesticide chemical registrants to secure the necessary data and should not issue new tolerances until such data are available.

C. EPA Failed To Consider Worker Risk In Establishing These Tolerances.

The FQPA requires consideration of worker risk in establishing final tolerances. A tolerance is not considered safe under the statute unless there is a reasonable certainty that no harm will result "from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures *and all other exposures for which there is reliable information.*" 21 U.S.C. § 346a(b)(2)(A)(ii) (emphasis added). Worker exposure is clearly included in this catch-all category of "all other exposures" to be considered in setting a tolerance. In establishing tolerances for isoxadifen-ethyl, acetamiprid, propiconazole, furilazole, fenhexamid, and fluazinam, EPA cites no provision of the statute or any other authority to support its repeated incantation that aggregate exposure "does not include occupational exposure." 66 Fed. Reg. 33,180 (isoxadifen-ethyl); 67 Fed. Reg. 14,650 (acetamiprid); 64 Fed. Reg. 2995 (propiconazole); 67 Fed. Reg. 15,728 (furilazole); 67 Fed. Reg. 19,114-15 (fenhexamid); 67 Fed. Reg. 19,121 (fluazinam). The statute's provision stating that EPA "shall consider, *among other relevant factors*...available information concerning the aggregate exposure from other non-occupational sources" does not justify ignoring farmworkers' exposure in setting tolerances. 21 U.S.C. § 408(b)(2)(D) (emphasis added). This provision explicitly requires EPA to consider "relevant factors" other than those enumerated, and is plainly illustrative rather than exhaustive. Moreover, much of farmworkers' elevated exposure comes not only from their occupational activities, but also because of the high exposures in the homes in which they live, the air they breathe, the water they drink. Clearly farmworkers are a high risk population deserving of careful

consideration and protection.[4] EPA's failure to consider worker risks in establishing these tolerances violates the FQPA's mandate that aggregate exposure assessments include *all* exposures for which there is reliable information. 21 U.S.C. § 346a(b)(2)(A)(ii).

D. The Aggregate Risk Assessment Is Inadequate.

The FQPA, 21 U.S.C. § 346a(b)(2)(A)(ii) requires that, to establish a pesticide tolerance, there must be a "reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." Aggregate exposure is the total exposure to a single chemical or its residues that may occur from dietary (*i.e.*, food and drinking water), residential, and all known or plausible exposure routes (including oral, dermal and inhalation). *See id.* Therefore, in addition to food and water exposures, the aggregate assessment must take into account exposures due to air drift and migration of contaminated soil, residential exposures from registered uses, and residential "take-home" exposures to families of those directly exposed to the pesticides through its

[4] Fiedler N, Kipen H, Kelly-McNeil K, Fenske R. Long-term use of organophosphates and neuropsychological performance. Am J Ind Med 1997; 32:487-96; Blair A, Grauman DJ, Lubin JH, Fraumeni JF, Jr. Lung cancer and other causes of death among licensed pesticide applicators. J Natl Cancer Inst 1983; 71:31-7; Blair A, White DW. Leukemia cell types and agricultural practices in Nebraska. Arch Environ Health 1985; 40:211-4; Blair A. Herbicides and non-Hodgkin's lymphoma: new evidence from a study of Saskatchewan farmers. J Natl Cancer Inst 1990; 82:544-5; Ji BT, Silverman DT, Stewart PA, et al. Occupational exposure to pesticides and pancreatic cancer. Am J Ind Med 2001; 39:92-9; Cantor KP, Blair A, Everett G, et al. Pesticides and other agricultural risk factors for non-Hodgkin's lymphoma among men in Iowa and Minnesota. Cancer Res 1992; 52:2447-55; Hoar SK, Blair A, Holmes FF, Boysen C, Robel RJ. Herbicides and colon cancer. Lancet 1985; 1:1277-8; Hoar SK, Blair A, Holmes FF, et al. Agricultural herbicide use and risk of lymphoma and soft-tissue sarcoma. Jama 1986; 256:1141-7; Zahm SH, Weisenburger DD, Saal RC, Vaught JB, Babbitt PA, Blair A. The role of agricultural pesticide use in the development of non- Hodgkin's lymphoma in women. Arch Environ Health 1993; 48:353-8; Zahm SH, Blair A. Pesticides and non-Hodgkin's lymphoma. Cancer Res 1992; 52:5485s-5488s; Zahm SH, Blair A. Cancer among migrant and seasonal farmworkers: an epidemiologic review and research agenda. Am J Ind Med 1993; 24:753-66; Zheng T, Zahm SH, Cantor KP, Weisenburger DD, Zhang Y, Blair A. Agricultural exposure to carbamate pesticides and risk of non-Hodgkin lymphoma. J Occup Environ Med 2001; 43:641-9.

agricultural uses. Furthermore, the aggregate assessment must consider exposures from uses that do not conform with the label, if there is an indication that such uses occur.

EPA failed to conduct an adequate aggregate assessment in establishing tolerances for isoxadifen-ethyl, acetamiprid, propiconazole, furilazole, fenhexamid, and fluazinam. First, all of the exposure data gaps outlined above in section III.A. constitute missing information that properly should have been incorporated into EPA's aggregate exposure assessment. Also, none of the regulations establishing tolerances for these six pesticides consider exposure through air drift, migration of contaminated soil, or residential take-home exposures. The isoxadifen-ethyl, acetamiprid, and fluazinam aggregate assessments suffer from an additional defect: EPA relied on unsupported and apparently arbitrary processing factors to reduce estimates of dietary exposure. 66 Fed. Reg. 33,182 (isoxadifen-ethyl); 67 Fed. Reg. 14,654 (acetamiprid); 67 Fed. Reg. 19,126 (fluazinam).

For all six pesticides, EPA incorrectly concluded that the new tolerances would not result in any increased residential exposure because the tolerances themselves were not for residential uses. 66 Fed. Reg. 33,183 (isoxadifen-ethyl); 67 Fed. Reg. 14,654 (acetamiprid); 64 Fed. Reg. 2999 (propiconazole); 67 Fed. Reg. 15,732 (furilazole); 67 Fed. Reg. 19,117 (fenhexamid); 67 Fed. Reg. 19,126 (fluazinam). This ignores reliable data concerning take-home exposure resulting from agricultural uses.[5] NRDC's 1998 report, *Trouble on the Farm*, documents the scientific evidence supporting the potential for take-home exposures from pesticides, even when not registered for residential use. *See* NRDC, *Trouble on the Farm: Growing up with Pesticides in Agricultural*

Communities, 1998. As many as a dozen different pesticide residues have been found in household dust in some homes, including agricultural insecticides and herbicides not registered for use in the home. *See* NRDC, *Farm Kids Petition* at 3.

The above deficiencies reveal that EPA improperly underestimated aggregate exposure to these pesticides and their residues that may occur from dietary, residential, and all other known or plausible exposure routes. The assumptions and missing data in EPA's analysis of aggregate exposure for these six pesticides systematically serve to underestimate exposure and therefore underestimate risk, contrary to the requirements of the FQPA.

E. EPA Improperly Failed To Rely On A NOEL For Dietary Risk Estimates.

EPA cannot lawfully establish tolerances in the absence of a no-observed-effect-level (NOEL). The report of the House Committee on Commerce clearly states its intent for all safety factors to be applied to the NOEL. *See* H.R. Rep. No. 104-669, Part 2, at 43, presented to the House on July 23, 1996. By using a NOEL, the risk assessor is assured that regulatory decisions are based on a dose at which no effect is elicited. The use of a lowest-observed-adverse-effect-level (LOAEL) or no-observed-adverse-effect-level (NOAEL) carries no such assurances. "Adverse" effects are often crude toxicological endpoints, such as death or dramatic loss of body or organ weight, and are not designed to coordinate to the vulnerable points in embryonic development. A LOAEL and even a NOAEL may represent a dose high enough to elicit significant unpleasant and harmful effects, and can not be considered as protective as a true NOEL.

---

[5] Lu C, Knutson DE, Fisker-Andersen J, Fenske RA. Biological monitoring survey of organophosphorus pesticide exposure among pre-school children in the Seattle metropolitan area. Environ Health Perspect 2001; 109:299-303

For isoxadifen-ethyl, acetamiprid, propiconazole, furilazole, fenhexamid, and fluazinam, EPA repeatedly failed to regulate on the basis of a NOEL. 66 Fed. Reg. 33,182 (isoxadifen-ethyl); 67 Fed. Reg. 14,652, 14,653 (acetamiprid); 64 Fed. Reg. 2998 (propiconazole); 67 Fed. Reg. 15,729 (furilazole); 67 Fed. Reg. 19,116 (fenhexamid); 67 Fed. Reg. 19,124 (fluazinam). For fluazinam in particular, EPA relied only on a LOAEL for dermal toxicity, and was unable to discern a NOAEL for this toxic effect of the pesticide. 67 Fed. Reg. 19,121. EPA also assessed only a LOAEL for dietary studies of fluazinam in mice and rats. 67 Fed. Reg. 19,124.

Lacking a NOEL for these endpoints, EPA has no scientific basis upon which to conclude that there is a fully safe level at which infants and children will not suffer developmental harm because of exposure to isoxadifen-ethyl, acetamiprid, propiconazole, furilazole, fenhexamid, or fluazinam. Therefore, EPA cannot make a legal finding that any specific residue of these pesticides on food is "safe" for infants and children, or that there is a "reasonable certainty of no harm" to infants and children at any specific level. 21 U.S.C. § 346a(b)(2). As a matter of law, under 21 U.S.C. § 346a(b)(2), EPA may not establish these new tolerances.

F. EPA Failed To Ensure A Reasonable Certainty Of No Harm For <u>All</u> Infants And Children In Establishing These Tolerances.

Under the FQPA, EPA must ensure that there is a reasonable certainty that no children will be harmed through exposure to pesticide chemical residues. 21 U.S.C. § 346a(b)(2)(C). If the best evidence suggests that thousands of children or more will exceed the reference dose for a pesticide, EPA is barred by statute from finding a reasonable certainty of no harm to these particular infants and children, and the Agency may not issue a tolerance at that level.

However, in establishing tolerances for isoxadifen-ethyl, acetamiprid, and furilazole, EPA regulates dietary residues at only the *95th percentile*. 66 Fed. Reg. 33,183 (acute dietary exposure to isoxadifen-ethyl at the 95th percentile); 67 Fed. Reg. 14,654 (acute dietary exposure to acetamiprid at the 95th percentile); 67 Fed. Reg. 15,732 (acute dietary exposure to furilazole at the 95th percentile). This runs contrary to EPA's previous policy of using the 99.9th percentile child (which itself is inadequate to fully protect children). Regulation at the 95th percentile means that five percent of all American children under age six – *around 1.2 million children in all* – could exceed the chronic reference dose every day, based on the best information available to the agency. Isoxadifen-ethyl, acetamiprid, and furilazole are each used on common children's foods – isoxadifen-ethyl and furilazole on corn, and acetamiprid on grapes. No reading of the FQPA will support any approach that allows millions of children to exceed the reference dose. Regulating dietary residues of these pesticides at the 95th percentile violates the FQPA's requirement that EPA "ensure that there is a reasonable certainty that *no harm* will result to infants and children from aggregate exposure to the pesticide chemical residue." 21 U.S.C. § 346a(b)(2)(C)(ii)(I).

G. EPA Failed To Guarantee That Legal Food Will Be Safe Food Based On Exposure To Pesticide Chemical Residues Of Propiconazole and Fluazinam At The Tolerance Level.

To assess chronic dietary exposure, EPA relied on estimates of "anticipated residues" for propiconazole and fluazinam. 64 Fed. Reg. 2997-98 (propiconazole); 67 Fed. Reg. 19,125 (fluazinam). In doing so, EPA failed to account for the dietary exposure of a significant number of consumers who purchase produce at farmers markets, farm stands, and "pick-your-own" farming operations. Over 1.9 million people buy

vegetables and fruits from nearly 13,000 farmers, at more than 2,000 community-based farmers markets and farm stands in the United States. *See* National Association of Farmers' Market Nutrition Programs (http://www.nafmnp.org/). These consumers include pregnant women, infants, and children, and must be protected. By ignoring this significant community of consumers, EPA vastly underestimates dietary exposure and cannot ensure that exposure to residues of propiconazole or fluazinam at the tolerance level will be safe. Reliance on 21 U.S.C. § 346a(b)(2)(E) to factor in anticipated residues does not justify ignoring the known dietary exposure of potentially millions of consumers to residues of these pesticides at the tolerance level. EPA must ensure that the legal level of pesticide chemical residue – the established tolerance levels – are themselves safe. 21 U.S.C. § 346a(b)(2)(A).

IV. RELIEF REQUESTED

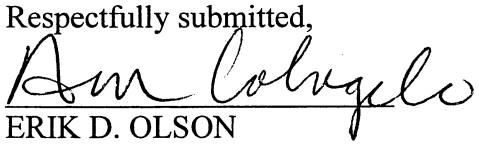
In light of the above outlined statutory violations, NRDC respectfully requests that EPA refrain from establishing the new tolerances for isoxadifen-ethyl, acetamiprid, propiconazole, fenhexamid, fluazinam, and furilazole until the pesticide tolerances have been assessed and determined to be safe consistent with the requirements of the FQPA.

V. REQUEST FOR A FEE WAIVER

Pursuant to 40 C.F.R. 180.33(m), NRDC hereby requests a waiver of all tolerance objection fees imposed by 40 C.F.R. 180.33(i). A waiver of fees will promote the public interest. NRDC is a national non-profit, tax-exempt public policy research and environmental organization. NRDC makes information available to thousands of citizens by means of its numerous and varied publications, educational programs, seminars, and public-interest litigation. These objections to the tolerances established for isoxadifen-

ethyl, acetamiprid, propiconazole, fenhexamid, fluazinam, and furilazole are intended to benefit primarily the public as opposed to NRDC. As outlined above, these objections challenge EPA regulations that fail to properly implement the FQPA and, as a result, pose threats to the public health, especially children's health. Furthermore, NRDC has no financial interest in the sale, manufacture, or use of isoxadifen-ethyl, acetamiprid, propiconazole, fenhexamid, fluazinam, furilazole, or any other pesticide. Requiring NRDC to pay the fees would work an unreasonable hardship.

Respectfully submitted,



ERIK D. OLSON
JON P. DEVINE, JR.
AARON COLANGELO
Natural Resources Defense Council
1200 New York Avenue, N.W., Suite 400
Washington, D.C. 20005
Phone: (202) 289-6868
Fax: (202) 289-1060

Dated: May 20, 2002